Appln. No.: 10/007,197

Amendment Dated May 24, 2004

Reply to Office Action of February 23, 2004

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

- 1. (Currently Amended) A pharmaceutical composition for treating or preventing mucositis comprising an effective amount of a poorly absorbed tetracycline which is not tetracycline or meclocycline in a carrier for topical administration to the mucosa, wherein the carrier for topical administration to the mucosa of the oral cavity and gastro-intestinal tract is selected from the group consisting of a mouthwash, lozenge, tablet, paste and gel and further wherein the tetracycline is in the form of a polyvalent metal ion complex.
- 2. (Previously Presented) The composition of claim 1 wherein the tetracycline is selected based on poor oral absorption from the group consisting of tetracyclines defined by the following structure:

wherein R_1 - R_5 are hydrogen atoms, halogen atoms, hydroxyl groups, or C1-8 groups which optionally include a heteroatom such as nitrogen, oxygen, in linear, branched, or cyclic structural formats.

- 3. (Original) The composition of claim 2 wherein R_1 and R_2 are hydrogen or a hydroxyl group; R_3 is hydrogen or a methyl group; R_4 is a hydrogen atom, a halogen, or a nitrogen containing entity; and R_5 is a hydrogen atom, or nitrogen containing ring structure.
- 4. (Withdrawn) The composition of claim 2 wherein the tetracycline is modified by substitution of H at carbon 9 by a substituted amido group.
- 5. (Original) The composition of claim 2 wherein the tetracycline is modified at any of positions 1 through 4 and 10 through 12.
- 6. (Original) The composition of claim 2 having the following structure:

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wherein R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , R^7 , and R^8 can be H, C1-C3 alkyl, phenyl, and aryl groups; and wherein X is an H, alkyl, alkoxy, phenoxy, aryloxy, amino group, amide, acyl, and halo group; and pharmaceutically acceptable salts thereof.

- 7. Cancelled.
- 8. Cancelled.
- 9. (Withdrawn) The composition of claim 1 wherein the carrier for topical administration comprises the tetracycline coated onto or encapsulated into a carrier selected from the group consisting of powders, pellets, microcapsules, liposomes, and emulsions.
- 10. (Withdrawn) The composition of claim 9 wherein the tetracycline is formulated as a dry powder.
- 11. (Original) The composition of claim 1 wherein less than 10% of the tetracycline is absorbed into the systemic circulation when topically administered to the mouth and then swallowed.
- 12. Cancelled.
- 13. (Currently Amended) The composition of claim $\frac{12}{2}$ wherein the polyvalent metal ion is calcium or magnesium.
- 14. (Withdrawn) The composition of claim 1 wherein the tetracycline is formulated to be topically administered to the mucosa as an aerosol.
- 15-24. Cancelled.